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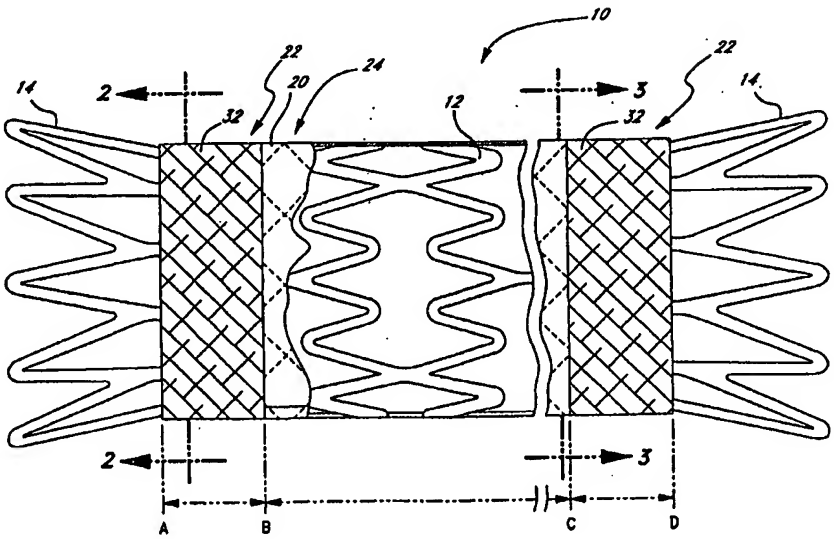

(57) Abstract

A portion of a covered stent is encapsulated with ePTFE, so that the unencapsulated portion, which is covered by a single ePTFE covering, of the stent unimpaired flexibility. One surface of the stent, either the luminal or abluminal surface, is covered by a single continuous layer of ePTFE, while limited regions, preferably near the ends of the stent, of the other surface are also covered by ePTFE. The regions covered by ePTFE on both surfaces become encapsulated when the ePTFE of one layer becomes bonded to second layer. By leaving a middle region of the stent unencapsulated, the stent retains flexibility similar to a bare stent, thereby reducing the loading and deployment forces.

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COVERED STENT WITH ENCAPSULATED ENDS

BACKGROUND OF THE INVENTION

This application claims the benefit of U.S. Provisional Application No. 60/118,269, filed February 02, 1999 which is incorporated herein by reference and U.S. Application No. 09/430,154 filed on October 29, 1999; this application is also a continuation in part of Application Serial No. 08/401,871, filed March 10, 1995, and Application Serial No. 08/508,033, filed July 27, 1995 and now issued as U.S. Patent 5,749,880 which are incorporated herein by reference.

1. Field of the Invention

The present invention relates generally to the field of medical devices, and more particularly, to the encapsulation of stents.

2. Description of Related Art

Stents and similar endoluminal devices are currently used by medical practitioners to treat tubular body vessels or ducts that become so narrowed (stenosed) that flow of blood or other biological fluids is restricted. Such narrowing (stenosis) occurs, for example, as a result of the disease process known as arteriosclerosis. While stents are most often used to "prop open" blood vessels, they can also be used to reinforce collapsed or narrowed tubular structures in the respiratory system, the reproductive system, bile or liver ducts or any other tubular body structure. However, stents are generally mesh-like so that endothelial and other tissues can grow through the openings resulting in restenosis of the vessel.

Polytetrafluoroethylene (PTFE) has proven unusually advantageous as a material from which to fabricate blood vessel grafts or prostheses, tubular structures that can be used to replace damaged or diseased vessels. This is partially because PTFE is extremely biocompatible causing little or no immunogenic reaction when placed within the human body. This is also because in its preferred form, *expanded* PTFE (ePTFE), the material is light and porous and is readily colonized by living cells so that it becomes a permanent part of the body. The process of making ePTFE of vascular graft grade is well known to one of ordinary skill in the art. Suffice it to say that the critical step in this process is the *expansion* of PTFE into ePTFE. This

expansion represents a controlled longitudinal stretching in which the PTFE is stretched to several hundred percent of its original length.

Apart from use of stents within the circulatory system, stents have proven to be useful in dealing with various types of liver disease in which the main bile duct becomes scarred or otherwise blocked by neoplastic growths, etc. Such blockage prevents or retards flow of bile into the intestine and can result in serious liver damage. Because the liver is responsible for removing toxins from the blood stream, is the primary site for the breakdown of circulating blood cells and is also the source of vital blood clotting factors, blockage of the bile duct can lead to fatal complications. A popular type of stent for use in the biliary duct has been one formed from a shape memory alloy (*e.g.*, nitinol) partially because such stents can be reduced to a very low profile and remain flexible for insertion through the sharp bend of the bile duct while being self-expandable and capable of exerting a constant radial force to the duct wall.

Cellular infiltration through stents can be prevented by enclosing the stents with ePTFE. Early attempts to produce a stent covered by ePTFE focused around use of adhesives or physical attachment such as suturing. However, such methods are far from ideal and suturing, in particular, is very labor intensive. More recently methods have been developed for encapsulating a stent between two tubular ePTFE members whereby the ePTFE of one-member touches and bonds with the ePTFE of the other member through the mesh opening in the stent. However, such a monolithically encapsulated stent may tend to be rather inflexible. Therefore, there is a need for a stent covered to prevent cellular infiltration and yet still flexible to ensure ease of insertion and deployment and to accommodate extreme anatomical curves.

SUMMARY OF THE INVENTION

The present invention is directed to covered stents wherein flexibility of the stent is retained, despite the use of encapsulation techniques. Encapsulation refers to the lamination of a stent between an inner and an outer layer of a plastic material. Compared to a fully encapsulated stent enhanced flexibility can be achieved by encapsulating limited regions of the stent, while leaving a significant portion of the stent—usually a middle portion—covered by a single layer of the plastic material. In this way the limited encapsulation fixes the plastic covering onto the stent with no need for sutures or similar labor intensive mechanical attachments.

It is an object of this invention to provide a stent device that has improved flexibility compared to a fully encapsulated stent, yet maintains its impermeability to infiltrating tissues.

It is yet another object of this invention to provide a stent device that shows minimal profile when loaded into insertion systems and can be deployed using forces that are reduced compared to those used with fully encapsulated designs.

These and additional objects are accomplished by embedding or encapsulating only portions of the stent between two layers of biocompatible material. This is accomplished by covering either the luminal or abluminal surface of the stent with a layer of biocompatible material, preferably ePTFE, while also covering limited sections of the opposite surface of the stent with the biocompatible material, thereby fully encapsulating only the limited sections. A preferred design fully encapsulates only the end regions of the device. By leaving a middle region of the stent unencapsulated, the stent is free to flex much like a bare stent, increasing overall flexibility and reducing the necessary loading and deployment forces.

In the present invention, a stent is partially encapsulated using the configuration mentioned above. One means of accomplishing this configuration is to place rings (radial strips) of ePTFE on a mandrel at positions corresponding to each end of the stent. The stent is then placed over the mandrel and the rings in registration with the ends of the stent. Finally, the stent (supported by the mandrel) is covered on its abluminal (outside) surface by a tubular ePTFE graft. The resulting structure is then subjected to heat and pressure so that the regions containing ePTFE on both surfaces become laminated or fused together (*e.g.*, a bond is formed). This

yields a stent with substantially its entire abluminal surface covered by ePTFE. Regions near the ends of the stent are fully encapsulated (*e.g.*, these regions are covered by ePTFE on their luminal surfaces as well). The fully encapsulated area serves to attach the abluminal covering to the stent.

A more complete understanding of the partial encapsulation of stents will be afforded to those skilled in the art, as well as a realization of additional advantages and objects thereof, by a consideration of the following detailed description of the preferred embodiment. Reference will be made to the appended sheets of drawings, which will first be described briefly.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of the preferred embodiment of the present invention.

Fig. 2 is a cross-sectional view along the line 2-2.

Fig. 3 is a cross-sectional view along the line 3-3.

Fig. 4 is an overview picture of the deployment of the device of the present invention.

Fig. 5 is a close-up view of the device being partially deployed.

Fig. 6 is a close-up view of the device fully deployed.

Fig. 7 is a picture of a fully encapsulated stent being tested for flexibility.

Fig. 8 is a picture of the covered stent of the present invention being tested for flexibility in the same manner as Fig. 7.

Fig. 9 shows an especially flexible stent design (the "Flexx" stent) preferred for use in the present invention; here the Flexx stent is shown in its expanded state.

Fig. 10 shows the flexible stent of Fig. 9 after it has been compressed.

Fig. 11 shows a close-up of the strut structure of the expanded stent of Fig. 9.

Fig. 12 shows a close-up view of the flexible stent design of Fig. 9 immediately after being cut from a metal tube and before being expanded into the form of Fig. 11.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention satisfies the need for a covered stent device that is virtually as flexible as an uncovered stent. This is accomplished by covering a stent on a first surface while limited regions are covered on the opposite surface to ensure fixation of the first surface covering.

Referring now to the drawings, in which like reference numbers represent similar or identical structures throughout, Fig. 1 illustrates a preferred embodiment of the present invention. A partially encapsulated stent-graft **10** is created by covering the abluminal surface of a stent **12** with a biocompatible barrier material that is able to seal fistulae and aneurysms and prevent or reduce tissue ingrowth from neointimal hyperplasia or tumor growth. In the preferred embodiment, the material used for this purpose is a tubular layer of expanded polytetrafluoroethylene (ePTFE) **20**. The preferred ePTFE is one optimized for bond strength as described in U.S. Patent 5,749,880. The stent **12** in the preferred embodiment is a shape memory alloy stent having geometry enhancing the stent's flexibility, although stents of a variety of designs are usable with the current invention because the inventive configuration minimizes the effect of the covering on stent flexibility. Also, the stent **12** can be made out of any type of material besides shape memory alloy.

It will be apparent to those of skill in the art that at a covering over at least one of the surfaces (luminal or abluminal) of the stent is necessary to prevent tissue ingrowth. Furthermore, the covering must be bonded to the stent to prevent it from coming detached and perhaps forming a blockage in the vessel. Although ePTFE has numerous favorable properties, it is relatively difficult to attach it to a stent. Mechanical fasteners such as sutures have the disadvantage of interrupting the integrity of the ePTFE sheet so that leaking can occur. Although ePTFE does not adhere well to a stent, it can be made to bond to itself. Therefore, one effective method of affixing the ePTFE cover is to place ePTFE covers in contact with both the abluminal and luminal surfaces of the stent so that one ePTFE covering can bond to the other where the ePTFE coverings touch through the openings in the stent. The drawback with this approach is that the structural members of the stent are tightly surrounded and held by ePTFE. When the stent bends or expands, the stent structural members must move relative to each other. This movement is resisted by the tightly

adhering ePTFE (or other covering material).

In the present invention movement of the stent members relative to each other is facilitated by limiting the region of the stent in which the structural members are surrounded (encapsulated) by ePTFE. In a preferred embodiment the regions of encapsulation, which ensure attachment of the covering to the stent, are limited to areas near the ends of the device. For a relatively short device these end-encapsulated regions are more than adequate to afford attachment of the covering. If necessary one or more additional regions of encapsulation could be added along the length of the device if it is found necessary for stability of the covering. Clearly, the greater the percentage of length of the device that is fully encapsulated, the more the flexibility of the overall structure will be impeded.

An additional advantage of the limited encapsulation of the present invention is the possibility of enhanced healing. It is known that living cells will infiltrate sufficiently porous ePTFE and that microcapillaries may form within and across the ePTFE wall so that a living intima is formed along the luminal surface. Where two layers of ePTFE surround the stent, it may be significantly more difficult for cellular infiltration across the wall to occur. Although the figures show the continuous covering placed on the abluminal surface of the device, the present invention also lends itself to placement of the continuous covering on the luminal surface. The configuration choice may depend on the precise application of the device. In some applications, for example large vessels having a high rate of blood flow placing the covering on the luminal surface may result in advantageous lamellar flow of the blood—blood flow without significant turbulence. There is some evidence that contact of the blood with a metal stent may result in local, limited thrombosis. While this may be detrimental, there is also some evidence that such limited thrombosis results in enhanced healing. An advantage of using a full luminal covering could be improved anchoring of the device within the duct or vessel afforded by interactions between the bare abluminal stent and the duct or vessel wall. Therefore, the optimal configuration will have to be empirically determined in many cases.

In the illustrated design (Fig. 1) the extremities **14** of the stent **12** are left completely uncovered and flare outward to facilitate anchoring of the stent within the vessel following expansion of the stent *in situ*. It will be apparent that this flared

region is a feature of this particular embodiment and is not a required element of the instant invention. The luminal surface of the stent **12** is covered at ends **22** defined between points A and B and points C and D in Fig. 1, but is left uncovered in mid-section **24** defined between points B and C. By leaving the mid-section **24** uncovered, the stent has increased flexibility as well as reduced profile when compressed. The material used to cover the ends **22** on the luminal surface of stent **12** is generally the same material that is used to cover the abluminal surface, and in Fig. 1 this material is ePTFE **30** (see Fig. 2), though any other suitable biocompatible material could be used in the present invention.

Again, it is important to note that while the continuous tubular layer of ePTFE **20** is shown on the abluminal surface of Fig. 1, it is possible, and advantageous in some cases, to place a tubular layer of ePTFE on the luminal surface, while placing limited rings of ePTFE only on the abluminal surfaces at the ends of the device. Distances A-B and C-D in Fig. 1 can be lesser or greater, depending on the need for flexibility in the particular application. Moreover, there can be any number of encapsulated region(s) and these region(s) can be located in different areas of the stent. Also, while the preferred embodiments use encapsulated regions that extend completely around a circumference of the device (*e.g.*, rings of material) as indicated by region **32** in Fig. 1, there is no reason that discontinuous regions of encapsulation cannot be used. Attaching discrete pieces or strips of ePTFE to a mandrel before the stent is placed on the mandrel can be used to form such discontinuous regions. The size, shape and pattern formed by regions **32** can be selected to enhance flexibility, etc. This allows different regions of the device to exhibit different properties of flexibility, etc.

Once the appropriate ePTFE covering is placed onto the luminal and abluminal surfaces, the ends **22** of the stent graft **10** are encapsulated by connecting or bonding the luminal covering to the abluminal covering. Encapsulation can be accomplished by a number of methods including sintering (*i.e.*, heating), suturing, ultrasonically welding, stapling and adhesive bonding. In the preferred embodiment, the stent-graft **10** is subjected to heat and pressure to laminate (bond) the tubular ePTFE layer **20** on the abluminal surface to the two rings of ePTFE **30** on the luminal surface.

Figs. 2 and 3 illustrate cross-sections of Fig. 1. A cross-section of stent-graft **10** is taken along line 2-2, through an end **22** of the device **10** in Fig. 2 and along line 3-3, through the mid-section **24** in Fig. 3. These two cross-sections are shown to illustrate the additional layer of ePTFE **30** that is present on the luminal surface of the end **22** and not present on the luminal surface of the mid-section **24**. As mentioned, the reason for encapsulating only the ends **22** of stent-graft **10** is to increase its flexibility over a fully encapsulated stent, thereby allowing it to be bent into extreme curves without kinking. Most of the length of the device is covered by only a single layer of ePTFE which is extremely flexible and which does not strongly interact with the stent. Therefore, the flexibility of the single layer area is essentially that of the underlying stent device. Fig. 7 shows a fully encapsulated shape memory alloy stent bent in essentially as sharp a curve as possible. Note that the covering material is showing kinks or distortions **34** due to the inability of the covering material to move longitudinally relative to the stent structural members. Fig. 8 shows an identical shape memory alloy stent covered according to the current invention: only the extreme device ends are fully encapsulated. Note that the device is capable of being bent into a much sharper curve with little or no distortion of the covering or the underlying stent.

An additional advantage provided by the present invention is that the retraction force necessary to deploy the stent-graft **10** using a coaxial deployment system is drastically reduced in comparison to a fully encapsulated stent. This is due to the reduction in amount of covering material. Furthermore, by reducing the amount of covering material, the overall profile of the deployment system is reduced, allowing a wider range of applications. Another advantage enjoyed by the present invention is its ease of manufacture compared to stent-graft devices that place multiple stent rings over ePTFE tubing. Finally, an advantage over stent-grafts with a single layer of biocompatible material over the entire graft length is that because a strong bond is created in the encapsulated region, it is possible to transmit a pulling force from one end of the stent of the present invention to the other via the covering, making it possible to load into a sheath using pulling techniques. The preferred bare stent designs (chosen for flexibility and low profile) do not permit transmission of a pulling force in a longitudinal axial direction. This is because

flexibility is increased and profile reduced by removing connections between longitudinally neighboring struts. The limited number of longitudinal connections has inadequate tensile strength to transmit the pulling force without failure. In the case of a true single layer covering (without use of adhesive, etc.) pulling on the covering causes the covering to slip off the stent. In the case of sutured single layer device pulling on the covering may cause the sutures holes to enlarge and even tear.

EXAMPLE 1

Two memotherm (shape memory alloy stent, product of Angiomed, Division of C. R. Bard, Inc.) biliary stents (S1 and S2), partially encapsulated according to the present invention, were loaded into a 10 French delivery system used for a standard covered biliary stent. The stents were 10 mm x 60 mm. The pulling force necessary to load the stents (the force between the outer sheath and the stent) was measured as follows:

S1 = 6.3N

S2 = 3.5N

In comparison, the loading force for a fully encapsulated stent is approximately 50N. After loading the samples S1 and S2 into a pullback delivery system, both were deployed into a glass biliary duct model placed in a 37°C water bath. All deployment went smoothly and no significant covering damage was observed. Thus, the partially encapsulated stents could be loaded employing a much-reduced force without being compromised structurally.

EXAMPLE 2

Three prototypes (P1, P2, and P3) were built using a Gamma 2 (Flexx) design memotherm stent, 12 mm x 120 mm. These prototypes were partially encapsulated according to the present invention. More particularly, the abluminal surface of each stent was covered with a tubular ePTFE material, leaving the regions near the stent ends uncovered (to flare outward and anchor the device). The luminal surface near each end of the stent was covered by a 9.95 mm ± 0.05 mm ring of ePTFE material. The stents were then subjected to heat and pressure so that the overlapping ePTFE material on the luminal and abluminal surfaces was bonded

together. The prototypes were then loaded into a 10 French delivery system and were deployed into a glass biliary duct model (45°, 25.4 mm radius) that was placed in a 37°C water bath.

The prototypes were loaded according to the standard loading technique used for loading fully encapsulated stents. This loading technique consists of compressing the stents by pulling them through a funnel using specially designed hooks. When loading the fully encapsulated stent, a backing mandrel and core are used to create a uniform folded pattern in the compressed stent. In loading P1, no backing mandrel and core inside the stent were used, resulting in an unacceptable load due to the presence of folds. P2 was loaded using a backing mandrel (9.2 mm diameter) and a core (1.25 mm diameter), resulting in a successful load with no folds. P3 was loaded in the same manner as P2. Loading forces between the funnel and the stent and pulling forces between the stent and the outer sheath were measured as follows:

Prototype	Peak Loading Force (N)	Peak Pulling Force (N)
P1	12.5	—
P2	27.5	12.9
P3	18.5	14.8

The loading force and pulling force necessary to load and deploy the prototypes were much smaller than that necessary for a fully encapsulated stent. Thus making it possible to load and deploy the prototypes with either a manual pullback or a pistol handgrip deployment system.

In the case of a biliary stent an especially tortuous delivery path must be used. There are two main techniques for such delivery. If the stent is deliver transhepatically, it is inserted through percutaneous vasculature, through the bulk of the liver and down the hepatic duct where it must make a bend of around 45 degrees between the hepatic and the bile duct. If the stent is delivered endoscopically it enters the bile duct via the papilla and must pass through multiple bends, the most sever of which is about 90 degrees with a 10 mm radius. Clearly an extremely flexible stent is required. To further illustrate the deployment of the prototypes, Figs. 4-6 have been provided. Fig. 4 shows an overview of the prototypes being deployed into a glass model of a bile duct using a pistol handgrip delivery system. Note the bend that the

stent must navigate. Fig. 5 shows a close-up view of a prototype, as it is partially deployed from the sheath. Fig. 6 shows a close-up view of a fully deployed prototype.

The "Flexx" stent used in these experiments is a specially designed stent configured for the present invention. Stents of this type are cut from tubes of Nitinol shape memory alloy and then expanded on a mandrel. The size memory of the device is set on the expanded form. The device is then compressed to the approximate dimensions of the original tube for insertion into a patient. Once properly located in the patient, the device is released and can self-expand to the "memorized" expanded dimension. Although the entire device is a single unitary piece, as shown in Fig. 9 in its expanded state, this design conceptually comprises a plurality of zigzag ring stents **64** (stenting zones) joined by longitudinal joining points **62**.

Fig. 10 shows the recompressed device to illustrate that each ring stent **64** is attached to each adjacent ring stent **64** by only a pair of joining points **64**. Note the open regions **60** between the joining points **62**. It will be apparent that such a structure affords considerable lateral flexibility to the entire compressed structure. If there were a larger number of joining points **64**, lateral flexibility of the compressed device would be impeded. On the other hand, the very open structure of the expanded stent (Fig. 9) offers little resistance to tissue infiltration.

These two factors account for the unusual suitability of the Flexx design in the present invention. The use of a covering of ePTFE or other biocompatible material prevents tissue infiltration despite the very open nature of the Flexx design. The use of end encapsulation (as opposed to encapsulation over the entire length of the device) preserves most of the inherent flexibility of the design. The use of only a single layer of covering over much of the stent results in a low profile in the compressed configuration so that the device can be inserted through small bile ducts and other restricted vessels. The use of only a very limited number of joining points **64** provides the lateral flexibility required for insertion through tortuous bile ducts and other similarly twisted vessels.

Fig. 11 is a close-up of a portion of Fig. 9 and shows the adjacent ring stents **64** (stenting zones) and the joining points **62**. Each ring stent **64** (stenting zone) is formed from a zigzag pattern of struts **54**. These struts have the thickness of the Nitinol tube from which the device is laser cut with a width, in this embodiment, of about 0.2 mm. There is a joining point **62** between a given ring stent **64** and an adjacent ring stent **64** every third strut **54** with the joining points **62** alternating from the left-hand adjacent to the right hand adjacent ring stent **64** so that six struts **54** separate the joining points **64** between any two ring stents **64**. Gaps **32** replace the joining points **62** where the intersections of zigzag struts are not joined.

Fig. 12 shows a close-up of the non-expanded cut structure of Fig. 10. Cuts **40**, **41**, and **42** are regions where the metal has been vaporized by a computer controlled cutting laser. The cut **40** between blind cuts **41** will expand to form the window **60**. Cut **42** forms the intersection point ✱ of the struts **54**, **which** show portions of two ring stents **64**. Partially cut regions **55** define a scrap piece of metal **32'**, which is removed following expansion to form the gaps **32**. In the figure the partially shown region above the cut **40** and above the scrap piece **32'** is the joining point **62**. Because a structure with only two joining pieces **62** between adjacent stent rings **64** is too fragile to withstand expansion as from Fig. 12 to Fig. 11, the scrap pieces **32'** act as reinforcing joining points for the radial expansion process. Following expansion the scrap pieces **32'** are removed to form the gaps **32**. This structure can then be deformed into the reduced diameter flexible structure shown in Fig. 10. It will be apparent that although this structure is described and pictured as having circumferential ring stents **64**, the stents zones can also be arranged in a helical manner to achieve the objects of the improved design.

Having thus described a preferred embodiment of the covered stent with encapsulated ends, it will be apparent by those skilled in the art how certain advantages of the present invention have been achieved. It should also be appreciated that various modifications, adaptations, and alternative embodiments thereof may be made. For example, while Flexx stent designs partially covered with ePTFE have been illustrated, it should be apparent that the inventive concepts described herein would be equally applicable to other types of stent designs and

biocompatible covering materials. Moreover, the words used in this specification to describe the invention and its various embodiments are to be understood not only in the sense of their commonly defined meanings, but to include by special definition in this specification structure, material or acts beyond the scope of the commonly defined meanings. The definitions of the words or elements of the following claims are, therefore, defined in this specification to include not only the combination of elements which are literally set forth, but all equivalent structure, material or acts for performing substantially the same function in substantially the same way to obtain substantially the same result. The described embodiments are to be considered illustrative rather than restrictive. The invention is further defined by the following claims.

CLAIMS

We Claim:

1. An implantable prosthetic device, comprising:

a stent;

a first layer of biocompatible material covering a majority of a first surface of the stent;

a second layer comprising a plurality of discrete pieces of biocompatible material covering a minority of a second surface of the stent; and

an encapsulated region wherein the first layer bonds to the second layer.

2. The implantable prosthetic device of Claim 1, wherein said a length of the first layer is less than a length of the stent and the first layer is disposed so that regions immediately adjacent to ends of the stent are not covered by the first layer.

3. The implantable prosthetic device of Claim 1, wherein said plurality of discrete regions comprises strips or rings placed at opposite ends of the second surface, leaving a mid-section of the second surface uncovered.

4. The implantable prosthetic device of Claim 1, wherein said first surface is the abluminal surface of the stent and said second surface is the luminal surface of the stent.

5. The implantable prosthetic device of Claim 1, wherein said first surface is the luminal surface of the stent and said second surface is the abluminal surface of the stent.

6. The implantable prosthetic device of Claim 1, wherein said first and second layers of biocompatible material comprise expanded polytetrafluoroethylene.

7. The implantable prosthetic device of Claim 1, wherein said stent comprises shape memory alloy.

8. An implantable prosthetic device, comprising:

a stent having a luminal and an abluminal surface and a first and a second end;

a first tubular layer of expanded polytetrafluoroethylene covering the abluminal surface of the stent;

a second tubular layer of expanded polytetrafluoroethylene, wherein the second layer comprises at least one ring disposed near the first or the second end of the stent in contact with a luminal surface thereof and leaving a majority of the luminal surface uncovered; and

an encapsulated region wherein the first tubular layer bonds to the second tubular layer.

9. The implantable prosthetic device of Claim 8, wherein said first layer does not cover a region immediately adjacent the first or the second end of the stent.

10. The implantable prosthetic device of Claim 8, wherein said stent comprises shape memory alloy.

11. The implantable prosthetic device of Claim 10, wherein said stent is formed by a method for forming a stent of expanded radius R from a tube of smaller radius r and wall thickness T comprising the steps of:

removing material form a wall of the tube over the full wall thickness T to leave the wall penetrated with a multiplicity of separate cut lines, in a pattern which permits the tube to expand to radius R;

expanding the tube to radius R where the cut lines define a plurality of zigzag struts forming stenting zones; and

removing a plurality of scrap portions that join adjacent stenting zones to form spacings between the adjacent stenting zones and to give the stent enhanced lateral flexibility when the stent is recompressed to radius r.

12. The implantable prosthetic device of Claim 8 further comprising a second ring of expanded polytetrafluoroethylene disposed at an opposite end of the stent from said at least one ring so that the device has two encapsulated regions with a non-encapsulated middle section therebetween.

13. A process for producing a flexible covered stent comprising the steps of:

providing a stent having a stent length;

placing a first tubular covering of expanded polytetrafluoroethylene, having a first covering length, in contact with one surface of the stent so that a majority of the surface is covered thereby;

placing a second tubular covering of expanded polytetrafluoroethylene, having a length substantially less than the first covering length, in contact with a second surface of the stent; and

forming an encapsulated region by bonding the first tubular covering to the second tubular covering and leaving a majority of the stent length unencapsulated.

14. The process of Claim 13 further comprising a step of placing a third tubular covering of expanded polytetrafluoroethylene, having a length substantially less than the first covering length, in contact with a second surface of the stent, wherein the second tubular covering and the third tubular covering are disposed in proximity to a first end and a second end of the stent, respectively, and wherein the step of forming an encapsulated region comprises bonding the first tubular covering to the second and to the third tubular covering.

15. The process of Claim 14, wherein the length of the first tubular covering is selected and one of the second and the third tubular covering is disposed so that one of the first end and the second end of the stent is left uncovered.

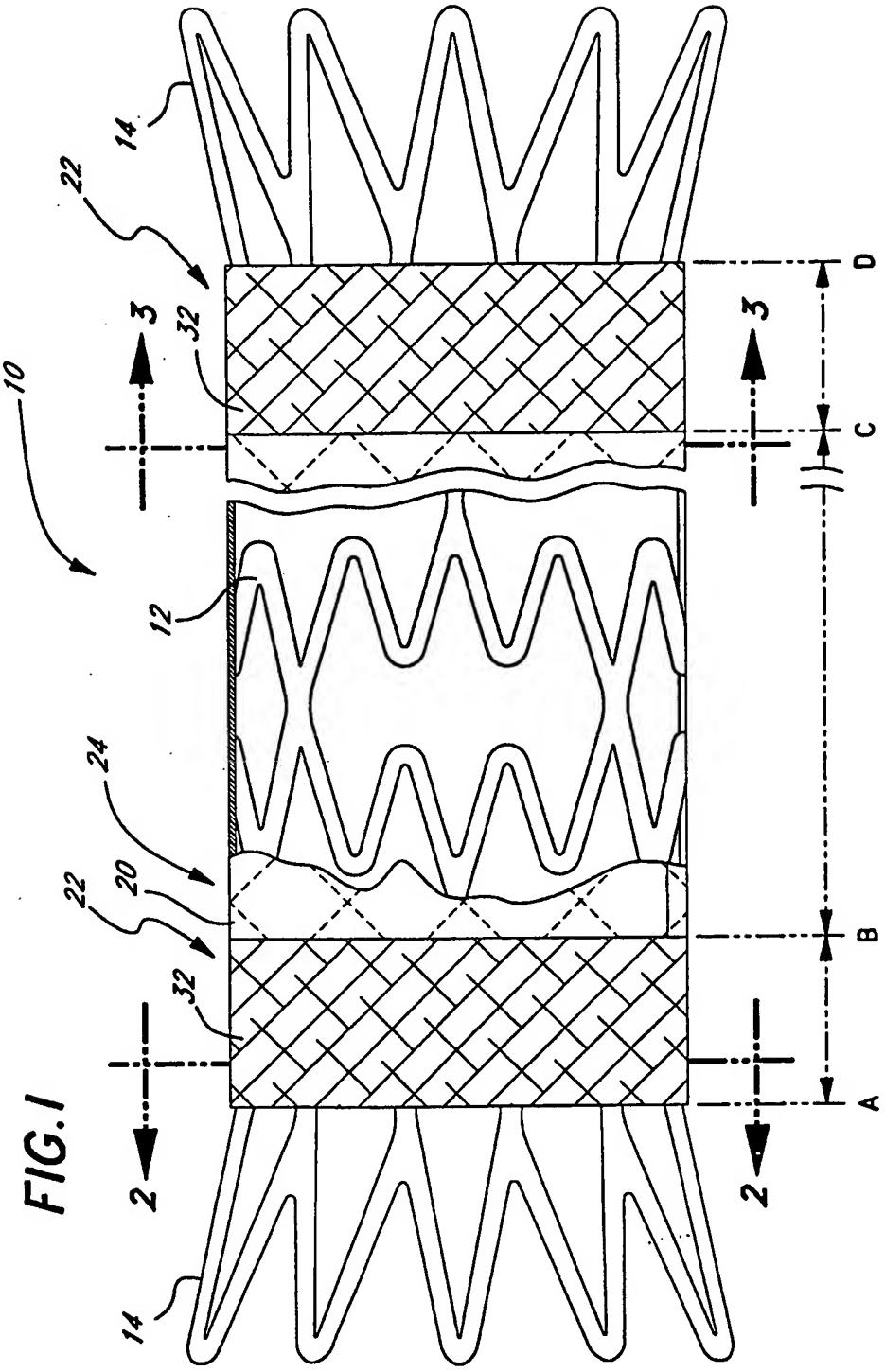

FIG. 1

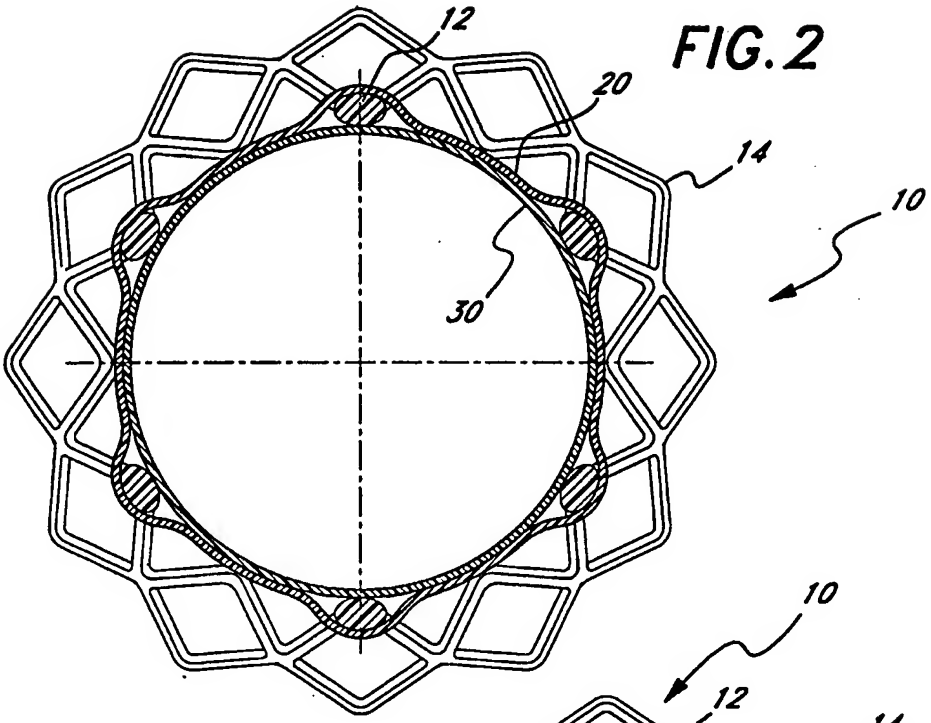

FIG. 2

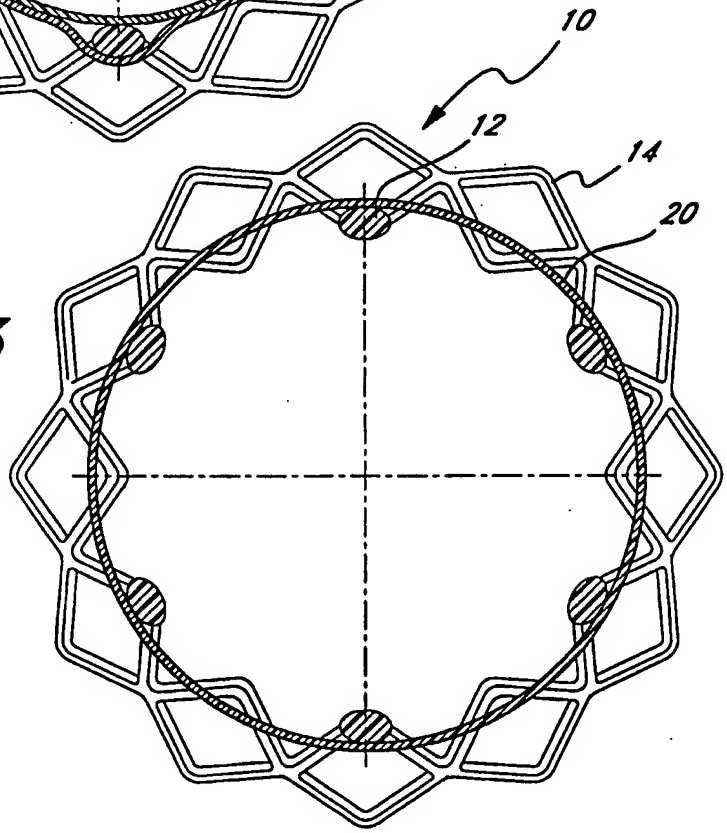

FIG. 3

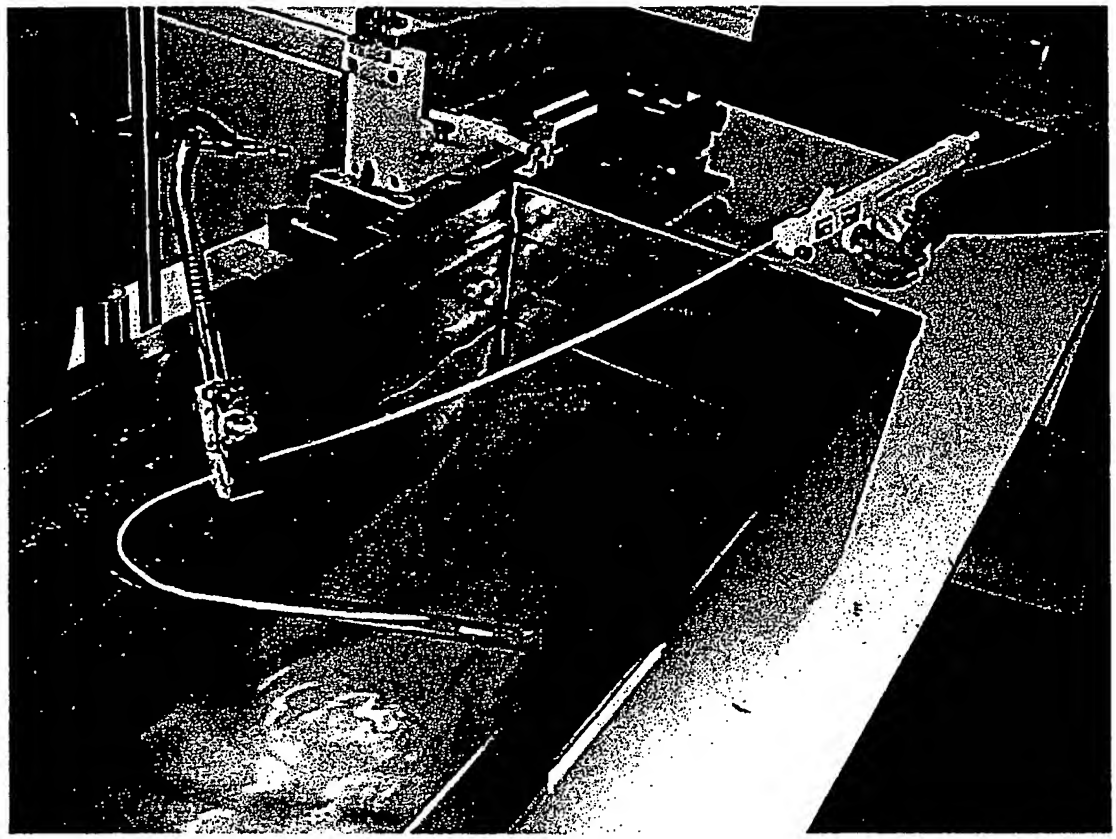

FIG. 4

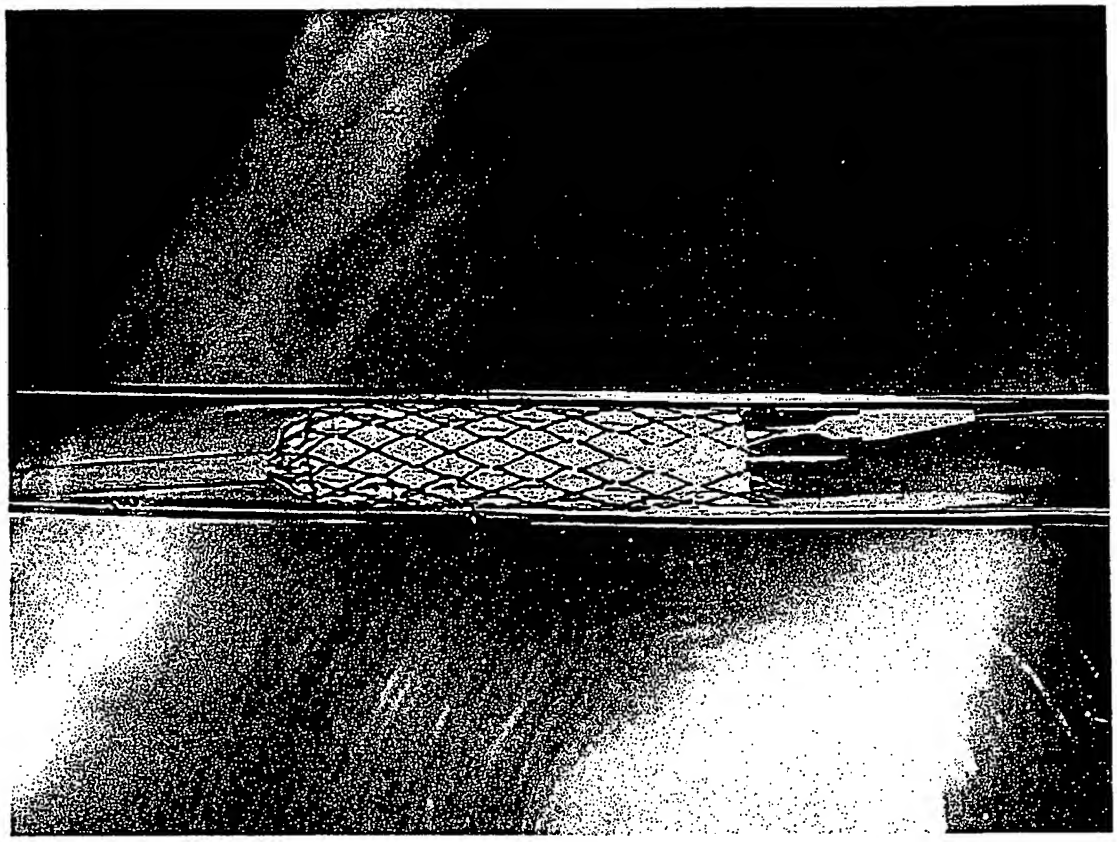

FIG. 5

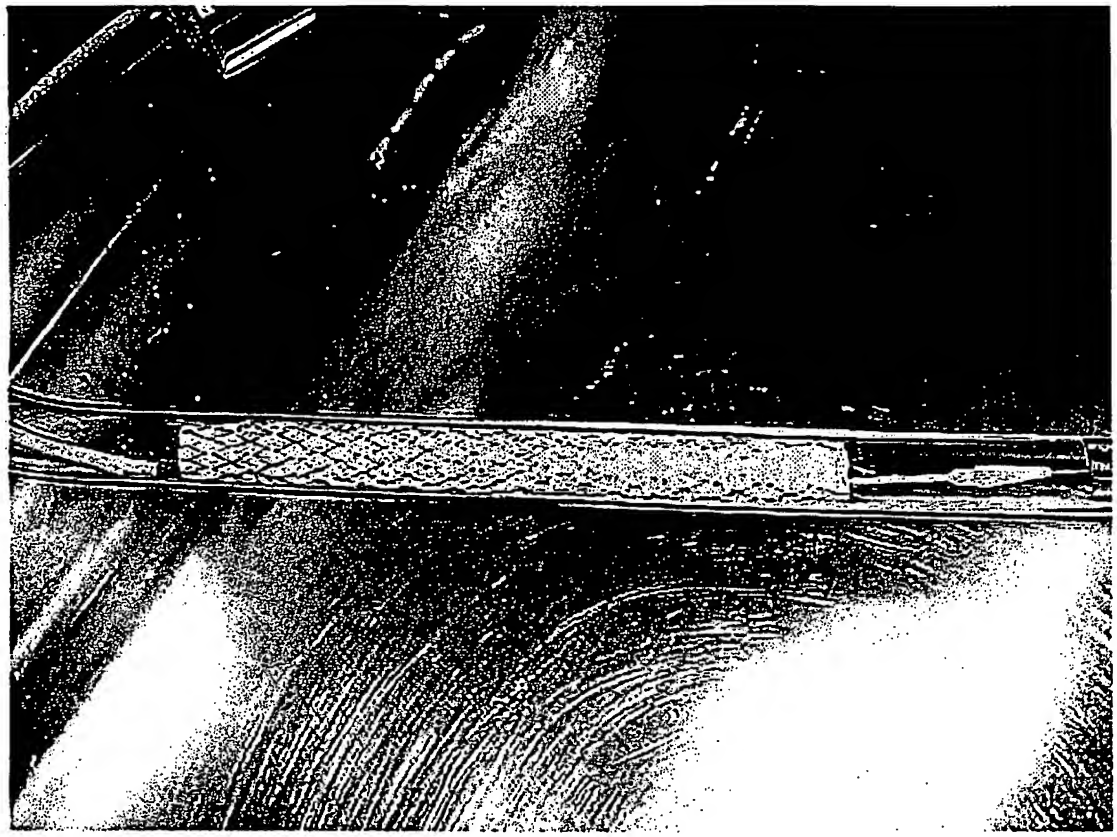

FIG. 6

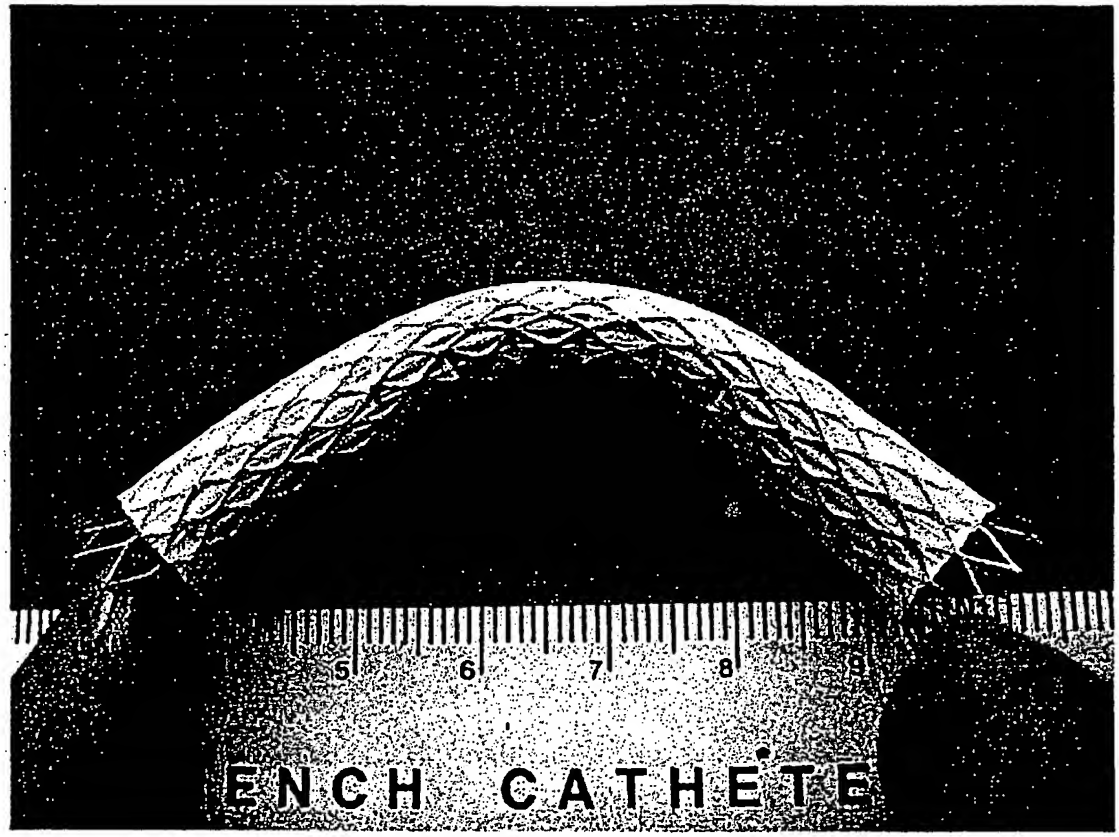

FIG. 7

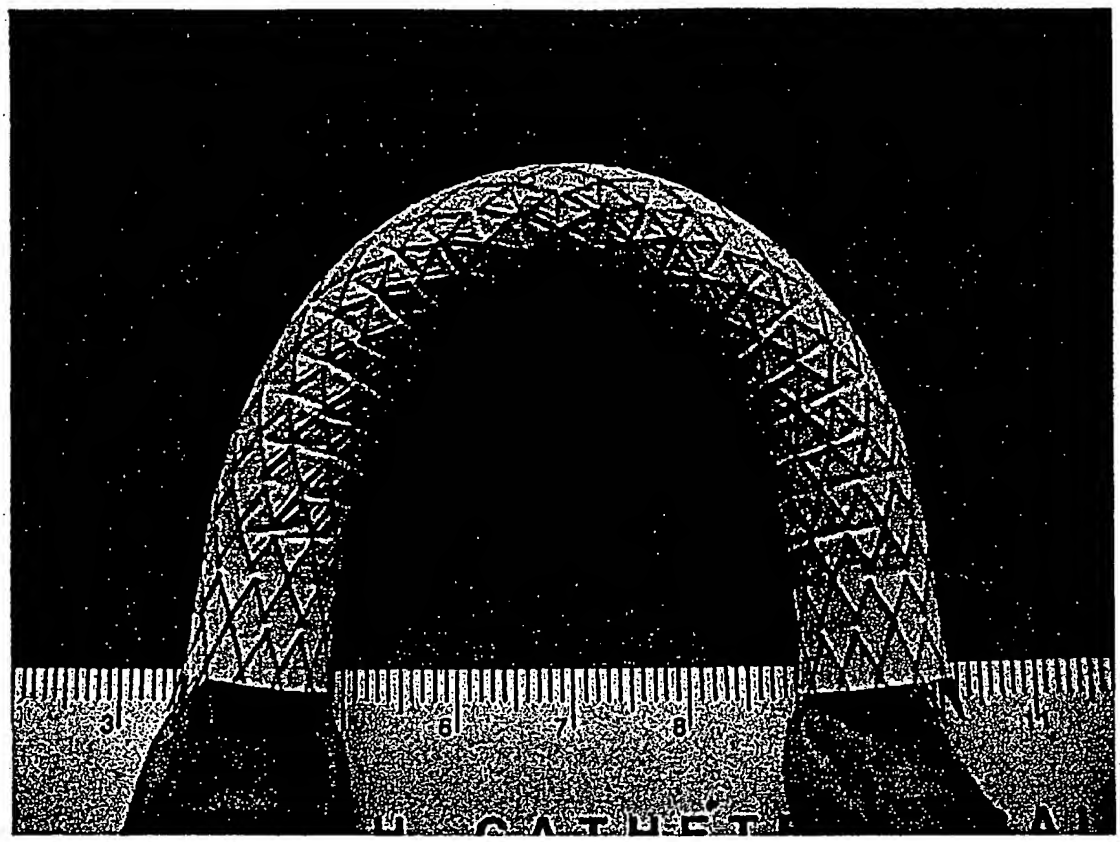

FIG. 8

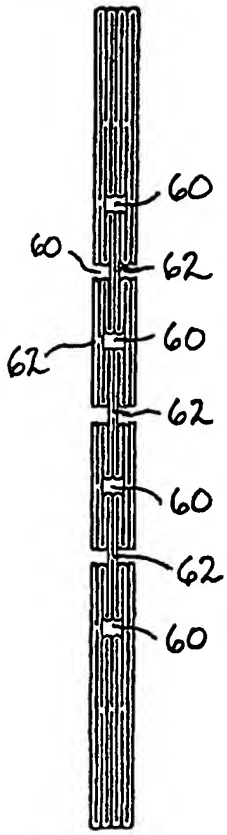

FIG. 10

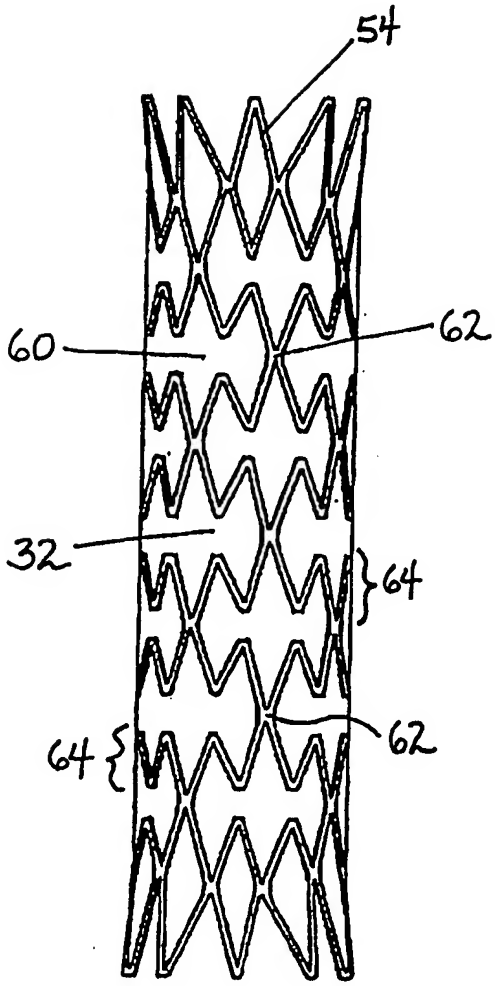

FIG. 9

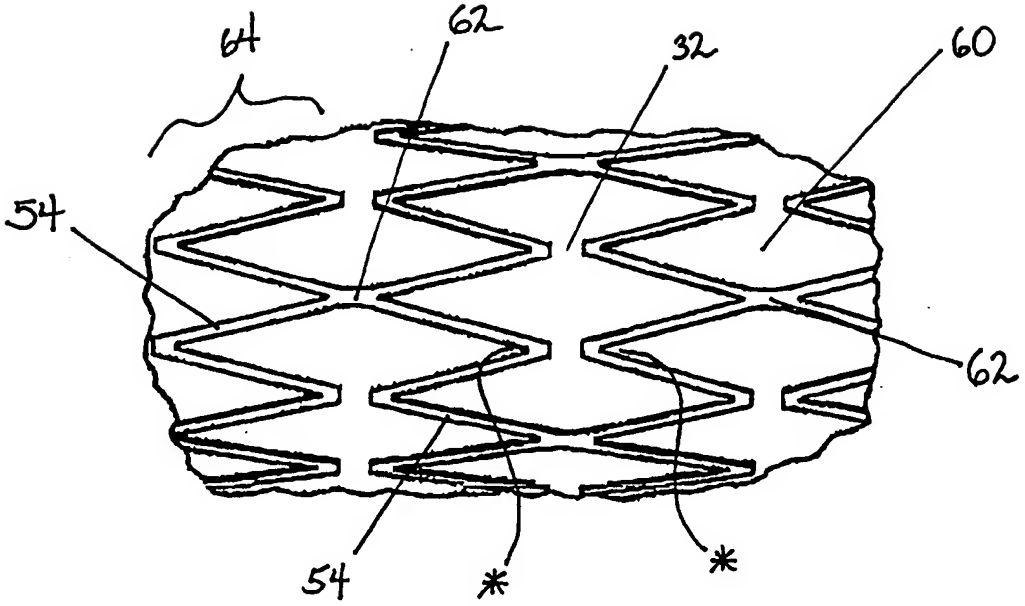

FIG. 11

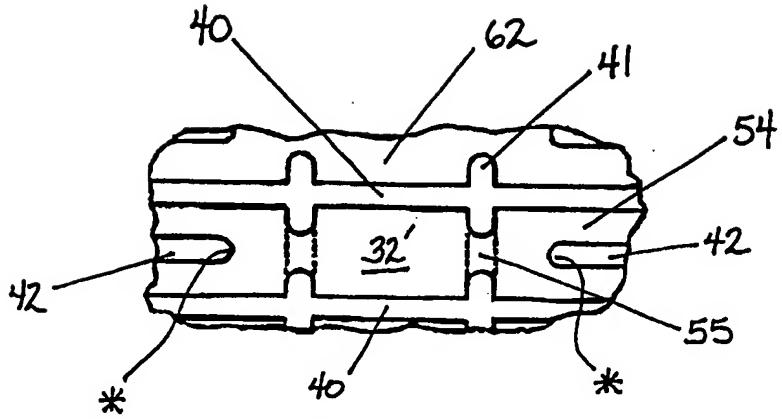

FIG. 12

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/02885

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 26731 A (ATRIUM MEDICAL CORPORATION) 25 June 1998 (1998-06-25) abstract; figures 10-15	1,8,13

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

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"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 July 2000	17/07/2000

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 00/02885

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9826731 A	25-06-1998	US 6010529 A	04-01-2000
		US 5897587 A	27-04-1999
		US 5824050 A	20-10-1998
		AU 5898498 A	15-07-1998
		EP 0971643 A	19-01-2000
		US 6042666 A	28-03-2000